

### REMARKS

In this Amendment, Applicant has cancelled Claim 3, without prejudice or disclaimer, and amended Claims 1 and 2. Claim 1 has been amended to specify certain embodiment of the present invention and overcome the rejection. Claim 2 has been amended to proper dependent form. It is respectfully submitted that no new matter has been introduced by the amendment. All claims are now present for examination and favorable reconsideration is respectfully requested in view of the preceding amendments and the following comments.

### REJECTIONS UNDER 35 U.S.C. § 103:

Claims 1 – 3 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over by Patel et al. (US 6,390,663), hereinafter Patel, in view of Stroppolo et al. (US 5,869,102), hereinafter Stroppolo, or Corbo et al. (US 6,551,617), hereinafter Corbo.

Applicant traverses the rejection and respectfully submits that the embodiments of present-claimed invention are not obvious over Patel, in view of Stroppolo, or Corbo. Claim 3 has been cancelled without prejudice or disclaimer. Therefore, the rejection to Claim 3 is moot. In addition, Claim 1 has been amended to clearly define that “colloidal silicon dioxide is used as a caking agent” to harden the emulsion of step (i).

It is respectfully submitted that the emulsion composition manufactured by the claimed steps containing 0.4 – 0.8 part by weight of diacetylated monoglycerides, 0.05 – 0.1 part by weight of sodium lauryl sulfate, and 0.005 – 0.01 part by weight of colloidal silicon dioxide is prepared to reduce the static electricity and to enhance the lubrication of film having good film distribution. However, the emulsion composition manufactured by the claimed steps does not provide any of (1) the effect as indicated in Patel for enhanced absorption of hydrophilic therapeutic agent; (2) the effect as indicated in Stroppoli as an excipient for ibuprofen; (3) the effect as indicated in Corbo for taste marking coating composition. None of Patel, Stroppolo, or Corbo is related to the present invention.

They fail to disclose or teach the claimed steps in using the diacetylated monoglycerides, sodium lauryl sulfate, and colloidal silicon dioxide at the specifically claimed ratio. In addition, as defined in the amended Claim 1, colloidal silicon dioxide is used as caking agent in the present invention (emphasis added). It is significantly different from the disintegrating agent as shown in Stroppolo and the processing aids as shown in Corbo.

More specifically, Stroppolo does not disclose the steps of preparing hardshell gelatin capsule. It merely discloses the mixture of (S)-Ibuprofen, microcrystalline cellulose, colloidal silica and magnesium stearate for filling of hard gelatine capsules (emphasis added, see col. 2, lines 35 – 39 and col. 3, lines 45 – 52). Therefore, Stroppolo only related to the filling mixture inside a gelatin capsule. However, the present invention as claimed is for preparation of hard gelatine capsules with specific characteristics of reducing static electricity and enhancing lubrication, without regard to what filling substance is in them. Therefore, Stroppolo is irrelevant to the present invention. Furthermore, the colloidal silica is used as disintegrating agent, which the present claimed invention requires that the colloidal silica dioxide used as caking agent. A disintegrating agent is for the mixture to rapidly disintegrate (See col. 7, 37 – 58, esp. example 7). A caking agent as defined in Claim 1 of the present invention is for hardening the emulsion obtained in step (i). Therefore, Stroppolo teaches away from the present invention. It further proves the unobviousness of the present invention as defined. Accordingly, Applicant respectfully submits that there is no motivation to combine Patel with either Stroppolo. Even if they are combined, they will not render the present invention as mended obvious.

Similarly, Corbo does not disclose the steps of preparing hardshell gelatin capsule. It merely discloses a coating composition of polyvinyl acetate, and a dimethylaminoethyl methacrylate and neutral methacrylic acid ester that masks the undesirable taste of a pharmaceutically active ingredient. Such coating agent is for filling of hard gelatine capsules (emphasis added, see col. 2, lines 16 – 20. Therefore, Stroppolo only related to the filling mixture inside a gelatin capsule. However, the present invention as claimed is for preparation of hard gelatine capsules with specific characteristics of reducing static electricity and enhancing lubrication, without regard to

what filling substance is in them. Therefore, Stroppolo is irrelevant to the present invention. Furthermore, the object of Corbo is to provide a coating that is insoluble in water and rapidly breaks down in an acid environment, such as stomach (See col. 2, line 3 – 9). However, the triglyceride-free compositions and methods of Patel require hydrophilic surfactant to be mixed with aqueous diluent, and resistance to dissolution and disintegration in the stomach (See Patel, col. 38, lines 65 – 67). Therefore, Corbo teaches away from Patel. The combination of components from Corbo with those of Patel is not enabled. There is simply no motivation to combine Corbo with Patel. Finally, the colloidal silica is only very briefly mentioned used as typical processing aids. However, colloidal silica as a typical processing aid is certainly different from colloidal silica used as a caking agent. Accordingly, Applicant respectfully submitted that there is no motivation to combine Patel with Corbo.

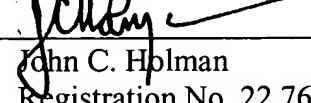
In summary, Applicant respectfully submits that there are significant differences between the embodiments of the present invention and the teaching of Patel, in view of Stroppolo, or Corbo. There is no motivation to combine Patel with either Stroppolo or Corbo. Even if they are combined, they will not render the present invention as mended obvious. Therefore, the newly presented claims are not anticipated by Patel, Stroppolo, or Corbo and the rejection under 35 U.S.C. §103(a) has been overcome. Accordingly, withdrawal of the rejections under 35 U.S.C. §103(a) is respectfully requested.

Having overcome all outstanding grounds of rejection, the application is now in condition for allowance, and prompt action toward that end is respectfully solicited.

Respectfully submitted,

JACOBSON HOLMAN PLLC

Date: January 10, 2005  
(202) 638-6666  
400 Seventh Street, N.W.  
Washington, D.C. 20004  
Atty. Dkt. No.: P66230US1

By   
John C. Holman  
Registration No. 22,769